

REMARKS

Reconsideration and withdrawal of the objections to and rejections of the application are respectfully requested in view of the amendments, remarks and enclosures herewith.

Claims 1 to 4, 6 to 10, 12 and 13 are now pending. No additional claim fee is due as there are 11 claims in total with one independent claim.

The Office Action, at page 2, asserts that the continuity paragraph is incomplete in not including information concerning U.S. application Serial No. 08/375,993, now U.S. Patent No. 5,688,512.

U.S. Patent No. 5,688,512 issued from U.S. application Serial No. 08/375,993, filed January 20, 1995 as a divisional of U.S. application Serial No. 08/079,601.

U.S. application Serial No. 08/079,601 issued as U.S. Patent No. 5,523,089 on June 4, 1996. The present application was filed January 19, 1996.

While the present application was copending with both U.S. applications Serial Nos. 08/079,601 and 08/375,993, there does not appear to be any need to claim priority from both of those applications. U.S. applications Serial Nos. 08/079,601 and 08/375,993 have the same specification (as the latter was a divisional of the former). The Declaration of Drs. Barbour and Luke establishes that the inventive entity of U.S. applications Serial Nos. 08/079,601 and 08/375,993 is not "another" as to the present inventive entity. And, Applicants only need start their lineage under Section 120 with a copending application; e.g., U.S. application Serial No. 08/079,601, and did not have to start their lineage with 08/375,993.

Accordingly, reconsideration and withdrawal of the objection to the continuity recitation are respectfully requested.

At page 2, paragraph 3, of the Office Action, the Examiner helpfully suggested some specification language; and, that language is amended by the specification amendments herewith, e.g., to update the status of an application and to rephrase it. No new matter is added.

A new Declaration and Power of Attorney is submitted herewith; and thus, it is respectfully requested that the objection to the oath or declaration at pages 2-3, paragraph 4, of the Office Action, be reconsidered and withdrawn.

Claim 5 was to be cancelled, without prejudice, by Examiner Sidberry; but, in view of her retirement, and a new Examiner on the application, claim 5 was not cancelled. Accordingly, claim 5 is herewith cancelled, without any prejudice; admission, surrender of subject matter, or any intention of creating any estoppel as to equivalents.

New claim 13 is presented herewith. Claim 13 depends upon claim 1 and calls for the composition to be for oral administration. No new matter is added (*see, e.g.*, claim 3). Further, as Applicants have presented a new claim, if any Office Action issues in the CPA, it **cannot** be a first Office Action Final Action; i.e., the first Office Action in the CPA (if there is any Office Action) must be non-final as Applicants have presented a new claim.¹

The objection to the drawings is noted and will be attended to upon receipt of a Notice of Allowance.

¹ However, it is noted that in view of the amendments, remarks and enclosures herewith, there should be no Office Action issuing; rather, the Examiner should be issuing a Notice of Allowance.

With respect to the obviousness-type double patenting rejection, at pages 3-4 and paragraphs 9-10 of the Office Action, it is respectfully submitted that the Examiner has failed to make a *prima facie* case of obviousness-type double patenting.

Double patenting of the "obviousness-type" exists when the subject matter of the claim in issue would have been obvious from that of the claim of a prior commonly assigned patent and *vice versa*. *Carman Industries, Inc. v. Wahl et al.*, 220 USPQ 481 (Fed. Cir. 1983). This reasoning was confirmed by the Court of Appeals for the Federal Circuit in *In re Braat*, 19 USPQ2d 1289 (Fed. Cir. 1991), wherein the Court stated:

We hesitate to characterize the Dil [cited patent] invention as an "improvement" over the Braat [rejected application] invention. The word "improvement" implies that it was developed specifically for use with the "basic" invention, and thus must have come later in time. . . .

However, we agree that the reasoning of *Borah* and Chisum, §9.03[2][c] is applicable in the present case. . . . A double patenting rejection is sustainable here only if claims 5/1 and 6/1 of Dil are not patentably distinct from the subject matter defined by the rejected claims of Braat, and the Board erred in sustaining the double patenting rejection without making such a "two-way" determination.

It is true that allowance of the Braat application will result in some timewise extension of [assignee] Philips' patent protection of the Dil structure. This is because Braat's claims dominate the invention of Dil claims 5/1 and 6/1. As our predecessor court pointed out in *Borah*, in analogizing the *Stanley* decision, "We see . . . that as a matter of law the extension of protection objection is not necessarily controlling." . . .

. . . There are situations where the extension is justified. See *Borah*; *In re Kaplan*, 798 F.2d 1574, 1577-78, 229 USPQ 678,

681-82 (Fed. Cir. 1986). This case presents such a situation. 19
USPQ2d at 1292 and 1293.

It is respectfully submitted that the Office Action fails to meet the criteria for an obviousness rejection, and misapprehends the law of double patenting.

As recently stated by the Federal Circuit:

The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious **unless the prior art suggests the desirability of the modification.**

In re Fritch, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) (emphasis added). *See also In re Kaplan*, 229 U.S.P.Q. 678, 683 (Fed. Cir. 1986) ("**there must be some clear evidence to establish why the variation [between claims of a patent and of the application] would have been obvious [for double patenting rejection] which can properly qualify as 'prior art' ... if obviousness predicated on the level of skill in the art, prior art evidence is needed to show what that level of skill was**"; and **only claims of patent or patent application, not its disclosure, available for use in double patenting rejection**).

Any dominance of the presently claimed subject matter by the claims of U.S. Patent No. 5,688,512 is not controlling in determining double patenting. *See In re Kaplan*, 229 U.S.P.Q. 678, 681 (Fed. Cir. 1986) ("**This commonplace situation [of one patent dominating another] is not, per se double patenting as the board seemed to think**").

The Office Action has not demonstrated that the required two-way obviousness exists, and fails to cite any evidence for why claims of U.S. Patent No. 5,688,512 are obvious in view of the present claims and *vice versa*.

More in particular, the present claims relate to a method for inducing an immunological response comprising mucosally administering a composition comprising substantially pure OspA; e.g., orally administering a composition comprising substantially pure OspA.

The Office Action has failed to demonstrate how the generic claims of U.S. Patent No. 5,688,512, in and of themselves (since the specificaiton of U.S. Patent No. 5,688,512 is unavailable to make the double patenting rejection) in any way particularly suggest either mucosal administration or oral administration.

The fact that U.S. Patent No. 5,688,512 claims a method for inducing a protective immunological response comprising administering a vaccine comprising substantially pure OspA is of no moment.

The Examiner must demonstrate that the generic claims of U.S. Patent No. 5,688,512 somehow specifically suggest mucosal or oral administration.

The fact that the claims of U.S. Patent No. 5,688,512 may dominate the present claims is not controlling. See *In re Kaplan, supra*. It is respectfully submitted that contrary to *In re Kaplan*, the Examiner is equating dominance with double patenting; and thus, the rejection is improper.

Mucosal or oral administration of substantially pure OspA can be patentably distinct from the generic claims of U.S. Patent No. 5,688,512. It is incumbent upon the Examiner to show how and why oral and mucosal administration are obvious from the generic recitation of "administering" in the claims of U.S. Patent No. 5,688,512. In this regard, the Examiner must show how and why oral and mucosal administration would have been suggested from the mere

recitation of “administering” in the claims of U.S. Patent No. 5,688,512. And, again, dominance of the present claims by the claims of U.S. Patent No. 5,688,512 is not controlling. *See In re Kaplan.*

Rather, in accordance with *Fritch* and *Kaplan*, the Examiner must demonstrate why and how it would have been obvious to modify “administering” in the claims of U.S. Patent No. 5,688,512 to oral administration or mucosal administration, based upon only the disclosure in the claims of U.S. Patent No. 5,688,512; for instance, why and how from just the claims of U.S. Patent No. 5,688,512 should one select oral or mucosal administration as opposed to intradermal, subcutaneous, intracutaneous, intramuscular, and all of the other ways one can “administer[]” substantially pure OspA, especially considering that the typical way a vaccine is administered is by injection, and not by oral or mucosal routes.

Having failed to so demonstrate why one should select oral or mucosal administration from all of the ways one can administer OspA based upon only the text of the claims of U.S. Patent No. 5,688,512, the obviousness-type double patenting rejection is fatally defective and cannot stand.

In further support of the proposition that U.S. Patent No. 5,688,512 can claim a genus which dominates the present claims but nonetheless the present claims can be patentably distinct, the Examiner is respectfully reminded that a species (or subgenus) may be patentably distinct from a genus such that a first patent issues to one party with claims directed to the genus, and a second patent issued to another party with claims directed to the species or subgenus. *See e.g., In re Baird*, 29 USPQ 2d 1550 (Fed. Cir. 1994); *In re Jones*, 21 USPQ 2d 1941 (Fed. Cir. 1992);

In re Taub, Wendler, and Slates, 146 USPQ 384 (C.C.P.A. 1965); *In re Petering*, 133 USPQ 275 (C.C.P.A. 1962); *Hsing v. Myers*, 2 USPQ2d 1861 (BOPAI 1987).

The Commentary to Rules of Practice, 49 Fed. Reg. 48416, 48433 (Dec. 12, 1984), 1050 O.G. 395 (Jan. 29, 1985), corrected to 50 Fed. Reg. 23122 (May 31, 1985), 1059 O.G. 27 (Oct. 22, 1985), provides in pertinent part:

Thus, if a species is patentable over a genus, the species is a "separate patentable invention" from the genus. Compare *In re Taub*, 348 F.2d 556, 146 USPQ 384 (C.C.P.A., 1965).

In this regard, the Examiner's attention is also directed to *In re Sasse*, 207 U.S.P.Q. 107 (C.C.P.A. 1980), wherein the Court of Customs and Patent Appeals held that a claim to a genus and a claim to a species within the genus are not claims to the same or substantially the same subject matter in the sense of 35 U.S.C. §135(b).

Essentially, if the present Applicants were strangers to the inventive entity of U.S. Patent No. 5,688,512 (but had the same effective filing date thereof of October 1988), the PTO would not declare and interference between the present application and U.S. Patent No. 5,688,512 because the claims of the present application and of U.S. Patent No. 5,688,512 would be deemed patentably distinct: the claims of U.S. Patent No. 5,688,512 being directed to a genus; and the present claims being directed to a patentably distinct subgenus or species (especially since there is nothing in the art, as of the October 1988 effective filing date of the present application, in any way teaching or suggesting oral or mucosal administration of OspA). The fact that the genus claims of U.S. Patent No. 5,688,512 dominate the present claims is of no moment.

Thus, the Office Action has not made any case of obviousness-type double patenting.

Simply, there is no basis in fact or law for the double patenting rejection.

The Office Action fails to show how the particular species or subgenus in the present claims - mucosally administering and orally administering - would be obvious from only the claims of U.S. Patent No. 5,688,512. And, the Office Action fails to show how the present claims are not a patentably distinct species or subgenus within the genus of the claims of U.S. Patent No. 5,688,512.

With respect to each of these points, it is again noted that only the claims of the present application and of U.S. Patent No. 5,688,512 are available to the Examiner, and not the disclosure of the present application or the specification of U.S. Patent No. 5,688,512.

Accordingly, there is no basis in fact or law for the double patenting rejection.

Reconsideration and withdrawal of the double patenting rejection based on U.S. Patent No. 5,688,512 are respectfully requested.²

Moreover, in view of the amendments, remarks and enclosures herewith, the present application is in condition for allowance.

Favorable reconsideration of the application, and prompt issuance of a Notice of Allowance, are earnestly solicited.

² It is respectfully submitted that Examiner Sidberry understood that no case of obviousness-double patenting had been made, and this is why she was willing to allow the application with the cancellation of claim 5. In this regard, the Examiner should consider that Examiner Sidberry was well aware of U.S. Patent No. 5,688,512, as she was the Examiner on the application which matured into that patent; and, the present Examiner should give full faith and credit to Examiner Sidberry's earlier determination of allowance of the application with only the cancellation of claim 5, i.e., of withdrawal of the obviousness-type double patenting rejection. For these reasons too, the present Examiner should reconsider and withdraw the obviousness-type double patenting rejection.

PATENT
454312-2420

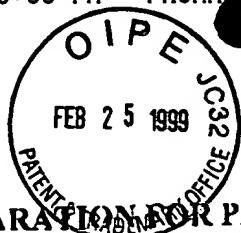
Although it is verily believed that the application is in condition for allowance, if any issue remains as an impediment to allowance, an interview is respectfully requested prior to any Office Action issuing; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By



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DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
 (Includes reference to PCT International Applications)

FROMMER LAWRENCE & HAUG, LLP
 File No.: 454312-2420

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor (if plural, names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention ENTITLED:

**COMPOSITIONS AND METHODS FOR ADMINISTERING
 BORRELIA BURGDORFERI ANTIGENS**

the specification of which:

is attached hereto

was filed on JANUARY 19, 1996 as:

United States Application Serial No. 08/588,637

PCT Application No. _____

with amendments through DATE EVEN HEREWITH (if applicable, give details).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code § 119 (a) - (d) or § 365 (b) of any foreign application(s) for patent or inventor's certificate, or § 365 (a) of any PCT International application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT International applications designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) on which priority is claimed:

Prior Foreign/PCT Application(s) [list additional applications on separate page]:

Priority Claimed:

<u>Country (or PCT)</u>	<u>Application Number:</u>	<u>Filed (Day/Month/Year)</u>	<u>Yes</u>	<u>No</u>
DENMARK	5902/88	24/10/88	X	

Prior Foreign/PCT Application(s) [list additional applications on separate page]:

Priority Claimed:

Country (or PCT) Application Number: Filed (Day/Month/Year) Yes No

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

(Application Number) (Filing Date)

I hereby claim the benefit under Title 35, United States Code § 120 of any United States application(s) or § 365 (c) of any PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior United States or PCT International application(s) in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S. (or U.S.-designating PCT) Application(s) [list additional applications on separate page]:

U.S. Serial No.: Filed (Day/Month/Year) PCT Application No. Status (patented, pending, abandoned)

08/079,601	22/06/93	5,523,089
07/924,798	06/08/92	ABANDONED
07/422,881	18/10/89	ABANDONED

I hereby appoint Thomas J. Kowalski, Registration No. 32,147, and FROMMER LAWRENCE & HAUG, LLP or their duly appointed associates, my attorneys or agents, with full power of substitution and revocation, to prosecute this application, to make alterations and amendments thereto, to file continuation and divisional applications thereof, to receive the Patent, and to transact all business in the Patent and Trademark Office and in the Courts in connection therewith, and to insert the Serial Number of the application in the space provided above, and specify that all communications about the application are to be directed to the following correspondence address:

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to the attention of:
Thomas J. Kowalski

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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NOTE: In order to qualify for reduced fees available to Small Entities, each inventor and any other individual or entity having rights to the invention must also sign an appropriate separate "Verified Statement (Declaration) Claiming [or Supporting a Claim by Another for] Small Entity Status" form [e.g. for Independent Inventor, Small Business Concern, Nonprofit Organization, Individual Non-Inventor].